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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/023,279	02/13/1998	JAY RUBINSTEIN	UIOWA-26	6755

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FLESHNER & KIM, LLP
14500 AVION PARKWAY
SUITE 125
CHANTILLY, VA 20151

EXAMINER

HARVEY, DIONNE

ART UNIT	PAPER NUMBER
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2643

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/023,279

Applicant(s)

RUBINSTEIN ET AL.

Examiner

Dionne N Harvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-11 13 15-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the signal generator, signal processor, the first signal, the second signal, the stimulation unit and the output combined signal according to the embodiment of claim 1; the pseudospontaneous generation means and its' associated drive signal, the auditory signal, the transducer means and its' associated electrical input signals and the stimulation means according to the embodiment of claim 16; the signal generator and its' associated second signal, the first signal, signal processor and its associated means for combining, stimulation unit, carrier signal, modulator and combined signal according to the embodiment of claim 22; and the method of modifying a neural prosthetic apparatus as described in claim 29, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13 and 15-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Specification fails to clearly enable one of ordinary skill in the art how to achieve a signal capable of inducing pseudospontaneous activity. Examiner acknowledges that the Applicant cites "...delivery of a high rate pulse train..." and "...broad band additive noise..." in the specification on pages 14 and 23, respectively. However, also on page 23, the Applicant states "...any signal that results in pseudospontaneous activity that meets the tests of independence...". The Examiner has taken the later recitation in combination with element (iii) in claim 21 as teaching that in addition to a pulse train and broadband noise, a signal having a frequency above approximately 2k Hz, would be capable of inducing pseudospontaneous activity.

However, in lite of the Applicant's arguments filed 2/19/04, the Examiner is no longer confident that the Applicant's specification clearly enables one of skill in the art to isolate said signal capable of inducing the claimed pseudospontaneous activity. The Applicant must definitively state those characteristics and/or tests of independence of a

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signal capable of inducing pseudospontaneous activity in a user, thus enabling a person skilled in the art to make or use the invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11,13,15-21,29-31 and any other applicable claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "pseudospontaneous activity". The Examiner is unclear about what the applicant means by his recitation of "pseudospontaneous activity". Clarification is required.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11,13,15,20,21,29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipka (US 6,377,693).

Regarding claims 11 and 15, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, in figure 2, Lipka teaches a method of

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generating a driving signal for an auditory implant, comprising: receiving a first signal (10); generating a second signal(22,12) that causes pseudo-spontaneous activity in an acoustic nerve; and applying the signals to the acoustic nerve. In column 2, lines 34-36, Lippa teaches that the applicator may be an electrode which directly applies the signal to a selected portion of the body. It is fair to conclude that for the invention of Lippa to be effective in the reduction of tinnitus and/or improving sensory response, the signal must reach the user's acoustic nerve. Lippa does not teach that the first and second signals are combined.

However, as discussed in the specification of the immediate application, specifically on page 28, beginning at line 11, the immediate inventor discloses that the first and second signals may be delivered separately to the auditory nerve. Since the combination of the first and second signals is not critical to the effectiveness and operation of said device, It would have been obvious for one of ordinary skill in the art at the time of the invention, to elect to combine the first and second signals for application to the acoustic nerve, as this would reduce the number of electrodes needed for implantation in the user.

Regarding claim 13, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, In column 2, lines 1-10, Lippa teaches that the first signal represents at least one of speech, emergency signals (as broadly claimed), and control information (as broadly claimed).

Regarding claim 20, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, since the second signal (22,12) represents auditory

stimuli, when the wearer in the absence of auditory stimuli, i.e., the second signal is thereby not applied.

Regarding claim 21, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, Lippa teaches that the second signal includes one of (i) a pulse train generating substantially continuous pseudospontaneous activity, (ii) a broad band noise, and (iii) at least fluctuations in amplitude greater than prescribed amount at a frequency above approximately 2k Hz that causes statistically independent activity in a plurality of nerve fibers of the nerve, wherein the driving signal is used to modulate a carrier signal.

Regarding claim 29, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, in figure 2, Lippa teaches a method of modifying a neural prosthetic apparatus that receives an information signal and supplies a corresponding electrical signal to stimulate an auditory nerve, comprising: providing a pseudospontaneous signal generator (12,22) that generates a second signal; and providing an electrical coupling means (16a) for supporting an electrical connection from the pseudospontaneous signal generator to at least one electrical contact (on the wearers body), and wherein the second signal is capable of inducing a random pattern of activation in the auditory nerve mimicking the spontaneous neural activity of the auditory nerve.

Regarding claim 30, as best understood with regard to the U.S.C. 112 first and second paragraph rejections above, In column 2, lines 1-10, Lippa teaches that the first signal represents at least one of speech, emergency signals (as broadly claimed), and

control information (as broadly claimed); and that the second signal includes one of (i) a pulse train generating substantially continuous pseudospontaneous activity, (ii) a broad band noise, and (iii) at least fluctuations in amplitude greater than prescribed amount at a frequency above approximately 2k Hz that causes statistically independent activity in a plurality of nerve fibers of the nerve, wherein the driving signal is used to modulate a carrier signal.

Response to Arguments

Applicant's arguments filed 2/19/04 have been fully considered but they are not persuasive.

1. With Regard To The Applicant's Argument That The Noise Generator (10) In Lippa Generates A Masking Signal Which Will Not Cause Pseudo-Spontaneous Activity In The Acoustic Nerve:

The Applicant has erroneously relied upon noise signal (10) as being the signal cited by the Examiner for anticipating the second signal of applicants claim 11 and 29. However, the Examiner has relied upon the combination of (12,22) as providing a high frequency signal applied via electrode (column 2, lines 34-36), not headphone or vibrational transducer as asserted by the Applicant, for anticipating the second signal which causes pseudo-spontaneous activity.

2. With Regard To The Applicant's Argument That Lippa Fails To Teach That The Second Signal Is "Broadband Noise" Or A "Pulse Train", And Therefore The

Sound Or Masking Signal Of Lippa Will Not Ever Generate Pseudo-Spontaneous Activity:

With regard to independent claims 11 and 29, the Applicant fails to include the specific recitation that defines the second signal as either "broadband noise" or "pulse train". Any arguments from the Applicant that Lippa fails teach these limitations, with regard to the fore-mention claims, are inapplicable. Additionally, according the Applicant's specification (page 23, lines 10-15), the medium for causing pseudo-spontaneous activity is not limited only to "broadband noise" signals or "pulse train" signals. Therefore, based upon the Applicant's Specification and further evidenced by Applicant's claim 21, an electrical signal having an amplitude greater than 2k Hz, would be capable of inducing pseudo-spontaneous activity. This is based upon the Applicant's own disclosure. As such, Lippa's high frequency signal (12,22) meets this limitation.

3. With Regard To The Applicant's Argument That Lippa Fails To Teach That The Pseudo-Spontaneous Activity Is Facilitated Via An Electrical Signal:

It appears that the Applicant has overlooked Lippa's teaching that the applicator (16) may be an electrode for directly applying the electrical signal to the user's body. Instead, the Applicant has erroneously argued that Lippa's teachings are limited to speakers or vibrational transducers. The Applicant further argues, with respect to claim 29, that Lippa discloses "...an electrode which directly applies an electromagnetic signal to a selected portion..." The Examiner is not clear how this argument distinguishes the immediate application from the Lippa reference.

The Examiner has interpreted said passage as being indicative of Lippa's use of microphone element-22 which may be constructed to include an electromagnetic transducer for pick-up of sound. In which case, said transmitted signal from said microphone-22 is an electromagnetic signal until its application to electrode applicator (16a). Unless the Applicant is asserting that the term "vibratory transducer" is interchangeable with "electrode", Lippa's clear teaching that the applicator may be implemented in electrode form, satisfies the limitations of the claims.

Conclusion

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statements for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111. The examiner can normally be reached on Monday through Friday from 8:30am to 6:00pm.

Any responses to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

or faxed to:

(703) 308-6306, for formal communications for entry

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Or:

(703) 308-6296, for informal or draft communications, please label "PROPOSED" or "DRAFT".

Hand delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor(Receptionist)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz, can be reached at (703) 305-4708.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111.

D.H.


HUYEN LE
PRIMARY EXAMINER